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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,887	08/08/2003	Daniel Rajotte	9/251	3401
28509	7590	03/08/2006		EXAMINER
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P O BOX 368 RIDGEFIELD, CT 06877-0368			RAMIREZ, DELIA M	
			ART UNIT	PAPER NUMBER
			1652	
			DATE MAILED:	03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/637,887	RAJOTTE ET AL.
	Examiner	Art Unit
	Delia M. Ramirez	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____.

DETAILED ACTION

Status of the Application

Claims 1-25 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 3-6, drawn in part to a fusion protein comprising a tryptase that specifically localizes to a secretory lysosome and a label polypeptide, classified in class 435, subclass 226.
 - II. Claims 3-4, 6, drawn in part to a fusion protein comprising a chymase that specifically localizes to a secretory lysosome and a label polypeptide, classified in class 435, subclass 226.
 - III. Claims 3-4, 6, drawn in part to a fusion protein comprising a carboxypeptidase that specifically localizes to a secretory lysosome and a label polypeptide, classified in class 435, subclass 212.
 - IV. Claims 3-12, drawn in part to a polynucleotide encoding a fusion protein comprising a tryptase that specifically localizes to a secretory lysosome and a label polypeptide, and a cell transformed with said polynucleotide, classified in class 536, subclass 23.4.
 - V. Claims 3-4, 6-11, drawn in part to a polynucleotide encoding a fusion protein comprising a chymase that specifically localizes to a secretory lysosome and a label polypeptide, and a cell transformed with said polynucleotide, classified in class 536, subclass 23.4.
 - VI. Claims 3-4, 6-11, drawn in part to a polynucleotide encoding a fusion protein comprising a carboxypeptidase that specifically localizes to a secretory lysosome and a label

polypeptide, and a cell transformed with said polynucleotide, classified in class 536, subclass 23.4.

- VII. Claims 13, 15, 17-25, drawn in part to a method for detecting and quantifying degranulation wherein a cell expressing a fusion protein comprising a tryptase is used, classified in class 435, subclass 23.
- VIII. Claims 13, 15, 17-22, 25, drawn in part to a method for detecting and quantifying degranulation wherein a cell expressing a fusion protein comprising a chymase is used, classified in class 435, subclass 23.
- IX. Claims 13, 15, 17-22, 25, drawn in part to a method for detecting and quantifying degranulation wherein a cell expressing a fusion protein comprising a carboxypeptidase is used, classified in class 435, subclass 24.
- X. Claims 14, 16, 17-25, drawn in part to a method for detecting and quantifying inhibition or increase in degranulation in the presence of a test compound wherein a cell expressing a fusion protein comprising a tryptase is used, classified in class 436, subclass 86.
- XI. Claims 14, 16, 17-22, 25, drawn in part to a method for detecting and quantifying inhibition or increase in degranulation wherein a cell expressing a fusion protein comprising a chymase is used, classified in class 436, subclass 86.
- XII. Claims 14, 16, 17-22, 25, drawn in part to a method for detecting and quantifying inhibition or increase in degranulation wherein a cell expressing a fusion protein comprising a carboxypeptidase is used, classified in class 436, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-VI each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The nucleic acids of Groups IV-VI comprises purine and pyrimidine units, and the proteins of Groups I-III comprises amino acids, thus being structurally distinct molecules. The nucleic acids of

Groups IV-VI have other uses besides encoding the proteins of Groups I-III, such as a hybridization probe or in gene therapy. Further, the proteins of Groups I-III can be prepared by processes which are materially different from recombinant expression of the nucleic acids of Group IV-VI, such as by chemical synthesis, or by isolation and purification from natural sources.

3. The inventions of Groups I-III and IV-VI are members of an improper Markush group as the proteins of Groups I-III and the nucleic acids of Groups IV-VI do not have unity of invention according to MPEP § 803.02. While the proteins of Groups I-III are proteases, each of the proteins of Groups I-III have a different structure and different enzymatic function. As such, the nucleic acids of Groups IV-VI encode proteins of different structure and enzymatic function. Each of the nucleic acids of Groups IV-VI can be used to probe different targets, and each of the proteins of Groups I-III can be used to elicit different antibodies. Therefore, there is no unity of invention within the members of the Markush group as there is no shared common utility and there is no shared substantial structural feature disclosed as being essential to that utility.

4. Inventions IV-VI and VII-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells comprising the nucleic acids of Inventions IV-VI can be used in the methods of Inventions VII-XII as well as to produce the fusion proteins encoded by the nucleic acids of Inventions IV-VI.

5. Inventions I-III and VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the proteins of Inventions I-III are neither used nor made by the methods of Inventions VII-XII.

6. Inventions VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of inventions VII-XII comprise different steps, may use different products and produce different results.

7. Claim 1 links inventions I-III and claim 2 links inventions IV-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 2. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. As set forth in MPEP § 803, the criteria for a proper restriction between patentably distinct inventions requires that the inventions must be independent or distinct as claimed, and a search of all the inventions would impose a serious burden on the examiner. Groups I-XII have been shown to be independent or distinct, for the reasons set forth above. MPEP § 803 also indicates that a serious burden on the examiner may be *prima facie* shown if the Examiner shows by appropriate explanation either

separate classification, separate status in the art, or a different field of search. The inventions of Groups I-XII have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification. In addition, a search of all the inventions would require at a minimum a separate patented/non-patented literature search and a class/subclass search. These searches are not all co-extensive. Therefore a comprehensive examination of all groups would impose an undue burden on the Examiner. Thus, restriction for examination purposes as indicated is proper.

9. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on

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the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 5, 2006